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Inventor: Paula J. Bates

Serial No.: 10/607,455

Examiner: Phuong N. Huynh

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Date: June 26, 2003

Group Art Unit: 1644

Title: METHOD FOR THE
DETECTION OF APOPTOSIS

Confirmation No.: 3317

INFORMATION DISCLOSURE STATEMENT

M.S. –Amendment
Commissioner for Patents
P.O. Box 1450
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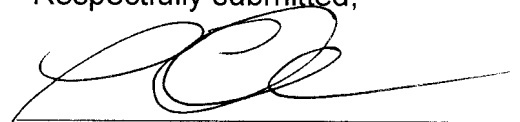
Dear Sir:

In accordance with the provisions of 37 C.F.R. § 1.56, Applicants request that citation and examination of the references identified on the attached Form PTO-1449, required copies of which are enclosed herewith in accordance with 37 C.F.R. §1.98, be made during the course of examination of the above-referenced application for United States Letters Patent.

Since this Information Disclosure Statement is being submitted after the mailing of the first Office Action, payment of the fee set forth in 37 C.F.R. §1.17(p) accompanies this submission.

- Payment by credit card.

Respectfully submitted,



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Form PTO-1449 (Rev. 8-88)	Attorney Docket No. LOU01-011-US	Serial No. 10/607,455
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)	First Named Inventor Paula J. Bates	
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Examiner Initials*		OTHER ITEMS - NON PATENT LITERATURE DOCUMENTS Include, as applicable: Author, Title, Date, Publisher, Edition or Volume, Pertinent Pages
	X2	Agrawal, S, et al, "Antisense therapeutics: is it as simple as complementary base recognition?", Mol Med Today, vol. 6, no. 2, pp. 72-81, (2000).
	X4	Aihara, M, et al, "Frequency of apoptotic bodies positively correlates with Gleason grade in prostate cancer", Hum Pathol, vol. 25, no. 8, pp. 797-801, (1994).
	X6	Altman, S, "Nobel lecture. Enzymatic cleavage of RNA by RNA", Biosci Rep, vol. 10, no. 4, pp. 317-337, (1990).
	X9	Andrade, F, et al, "Apoptosis in systemic lupus erythematosus", Rheumatic Diseases Clinics of North America, vol. 2, (2000).
	X10	Awang, G, et al, "Mode of dimerization of HIV-1 genomic RNA", Biochemistry, vol. 32, no. 42, pp. 11453-11457, (1993).
	X16	Barton, C.M, et al, "Antisense oligonucleotides directed against p53 have antiproliferative effects unrelated to effects on p53 expression", Br J Cancer, vol. 71, no. 3, pp. 429-437, (1995).
	X18	Beedassy, A, et al, "Chemotherapy in advanced prostate cancer", Semin Oncol, vol. 26, no. 4, pp. 428-438, (1999).
	X22	Bergsmedh, A, et al, "Horizontal transfer of oncogenes by uptake of apoptotic bodies", Proc Natl Acad Science USA, vol. 98, no. 11, pp. 6407-6411, (2001).
	X24	Bernardi, F.D, et al, "A prognostic model of survival in surgically resected squamous cell carcinoma of the lung using clinical, pathologic, and biologic markers", Mod Pathol, vol. 10, no. 10, pp. 992-1000, (1997).
	X30	Blau, H.M, et al, "Tet B or not tet B: Advances in tetracycline-inducible gene expression", Proc Natl Acad Science USA, vol. 96, pp. 797-799, (1999).
	X32	Borer, R.A, et al, "Major nucleolar proteins shuttle between nucleus and cytoplasm", Cell, vol. 56, no. 3, pp. 379-390, (1989).
	X34	Borst, P, et al, "Does resistance to apoptosis affect clinical response to antitumor drugs?", Drug Resist Update, vol. 4, no. 2, pp. 129-131, (2001).
	X39	Brown, J.M, et al, "Apoptosis: mediator or mode of cell killing by anticancer agents?", Drug Resist Update, vol. 4, no. 2, pp. 135-136, (2001).
	X40	Brustmann, H, "Apoptotic bodies as a morphological feature in serous ovarian carcinoma: correlation with nuclear grade, Ki-67 and mitotic indices", Pathol Res Pract, vol. 198, no. 2, pp. 85-90, (2002).
	X41	Burgess, T.L, et al, "The antiproliferative activity of c-myc and c-myc antisense oligonucleotides in smooth muscle cells is caused by a nonantisense mechanism", Proc Natl Acad Science USA, vol. 92, no. 9, pp. 4051-4055, (1995).
	X48	Cech, T.R, "Biologic catalysis by RNA", Harvey Lect, vol. 82, pp. 123-144, (1988).
	X49	Chern, J.H, et al, "Usefulness of AgNOR score in differentiating benign from malignant pulmonary aspiration cytology", Acta Cytol, vol. 41, no. 2, pp. 393-398, (1997).
	X51	Cole, S.P, et al, "Antibody production by human X human hybridomas in serum-free medium", J Immunol Methods, vol. 78, no. 2, pp. 271-278, (1985).
	X56	Crooke, S, "Progress in antisense technology: the end of the beginning", Methods Enzymol, vol. 313, pp. 3-45, (1999).
	X58	Dagle, J.M, et al, "Selective degradation of targeted mRNAs using partially modified oligonucleotides", Methods Enzymol, vol. 313, pp. 420-436, (1999).
	X59	Daniely, Y, et al, "Formation of a complex between nucleolin and replication protein A after cell stress prevents initiation of DNA replication", J Cell Biology, vol. 149, no. 4, pp. 799-810, (2000).
	X67	Deng, J.S, et al, "Internalization of anti-nucleolin antibody into viable HEP-2 cells", Mol Biol Rep, vol. 23, no. 3-4, pp. 191-195, (1996).

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	X69	Derenzini, M, et al, "The quantity of nucleolar proteins nucleolin and protein B23 is related to cell doubling time in human cancer cells", Lab Invest, vol. 73, no. 4, pp. 497-502, (1995).
	X79	Eguchi, K, "Apoptosis in autoimmune diseases", Intern Med, vol. 40, no. 4, pp. 275-284, (2001).
	X84	Fielding, P, et al, "Heterogeneous nuclear ribonucleoprotein A2/B1 up-regulation in bronchial lavage specimens: a clinical marker of early lung cancer detection", Clinical Cancer Research, vol. 5, no. 12, pp. 4048-4052, (1999).
	X86	Fry, M, et al, "The fragile X syndrome d(CGG)n nucleotide repeats form a stable tetrahelical structure", Proc Natl Acad Science USA, vol. 91, no. 11, pp. 4950-4954, (1994).
	X88	Gautier, F, et al, "Identification of an apoptotic cleavage product of BARD1 as an autoantigen: a potential factor in the antitumoral response mediated by apoptotic bodies", Cancer Research, vol. 60, no. 24, pp. 6895-6900, (2000).
	X107	Hanahan, D, et al, "The hallmarks of cancer", Cell, vol. 100, no. 1, pp. 57-70, (2000).
	X109	Hanakahi, L.A, et al, "Nucleolin is one component of the B cell-specific transcription factor and switch region binding protein, LR1", Proc Natl Acad Science USA, vol. 94, no. 8, pp. 3605-3610, (1997).
	X115	Hirsch, F.R, et al, "Early detection of lung cancer: clinical perspectives of recent advances in biology and radiology", Clinical Cancer Research, vol. 7, no. 1, pp. 5-22, (2001).
	X124	Iida, A, et al, "Inducible gene expression by retrovirus-mediated transfer of a modified tetracycline-regulated system", J Biol, vol. 70, no. 9, pp. 6054-6059, (1996).
	X129	Ishikawa, F, et al, "Nuclear proteins that bind the pre-mRNA 3' splice site sequence r(UUAG/G) and the human telomeric DNA sequence d(TTAGGG)n", Mol Cell Biology, vol. 13, no. 7, pp. 4301-4310, (1993).
	X132	Kamma, H, et al, "Interaction of hnRNP A2/B1 isoforms with telomeric ssDNA and the in vitro function", Biochem Biophys Res Commun, vol. 280, no. 3, pp. 625-630, (2001).
	X133	Kaneko, S, et al, "Nucleolar organizer regions as a prognostic indicator for stage I non-small cell lung cancer", Cancer Research, vol. 51, no. 15, pp. 4008-4011, (1991).
	X135	Keough, T, et al, "A method for high-sensitivity peptide sequencing using postsources decay matrix-assisted laser desorption ionization mass spectrometry", Proc Natl Acad Science USA, vol. 96, no. 13, pp. 7131-7136, (1999).
	X137	Ketting, R.F, et al, "Dicer functions in RNA interference and in synthesis of small RNA involved in developmental timing in C elegans", Genes Dev, vol. 15, no. 20, pp. 2654-2659, (2001).
	X138	Kibbey, M.C, et al, "A 110-kD nuclear shuttling protein, nucleolin, binds to the neurite-promoting IKVAV site of laminin-1", J Neurosci Research, vol. 42, no. 3, pp. 314-322, (1995).
	X141	Kohler, G, et al, "Continuous cultures of fused cells secreting antibody of predefined specificity", Nature, vol. 256, pp. 495-497, (1975).
	X142	Kohler, P.O, "Isolation, cloning, and hybridization of endocrine cell lines", Methods Enzymol, vol. 39, pp. 109-128, (1975).
	X143	Krantz, S, et al, "Purification and partial amino acid sequencing of a fructosyllysine-specific binding protein from cell membranes of the monocyte-like cell line U937", Biochim Biophys Acta, vol. 1266, no. 1, pp. 109-112, (1995).
	X145	Kumar, R.K, et al, "Improved double immunofluorescence for confocal laser scanning microscopy", J Histochem Cytochem, vol. 47, no. 9, pp. 1213-1218, (1999).
	X147	Lakka, S.S, et al, "Adenovirus-mediated antisense urokinase-type plasminogen activator receptor gene transfer reduces tumor cell invasion and metastasis in non-small cell lung cancer cell lines", Clinical Cancer Research, vol. 7, no. 4, pp. 1087-1093, (2001).
	X149	Larrucea, S, et al, "Internalization of factor J and cellular signalization after factor J-cell interaction", Biochem Biophys Res Commun, vol. 266, no. 1, pp. 51-57, (1999).

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	X152	Lebedeva, I, et al, "Antisense oligonucleotides: promise and reality", Annu Rev Pharmacol Toxicol, vol. 41, pp. 403-419, (2001).
	X159	Lopes de Menezes, D, et al, "Pharmacokinetics of Bcl-2 antisense oligonucleotide (G3139) combined with doxorubicin in SCID mice bearing human breast cancer solid tumor xenografts", Cancer Chemother Pharmacol, vol. 49, no. 1, pp. 57-68, (2002).
	X161	Ma J, et al, "Cells designed to deliver anticancer drugs by apoptosis", Cancer Research, vol. 62, no. 5, pp. 1382-1387, (2002).
	X171	McManus, M.T, et al, "Gene silencing in mammals by small interfering RNAs." Nat Rev Genet, vol. 3, no. 10, pp. 737-747, (2002).
	X174	Mehes, G, et al, "Nucleolin and fibrillarin expression in stimulated lymphocytes and differentiating HL-60 cells. A flow cytometric assay", Cell Prolif, vol. 28, no. 6, pp. 329-336, (1995).
	X180	Morgan, D.M, "Tetrazolium (MTT) assay for cellular viability and activity", Meth Mol Biol, vol. 79, pp. 179-183, (1998).
	X181	Morimoto, Y, et al, "Alteration of argyrophilic nucleolar organizer region associated (Ag-NOR) proteins in apoptosis-induced human salivary gland cells and human oral squamous carcinoma cells", J Oral Pathol Med, vol. 30, no. 4, pp. 193-199, (2001).
	X182	Morimoto, Y, et al, "Upregulation of the expression of Fas antigen and Fas ligand in a human submandibular gland ductal cell line by okadaic acid", Arch Oral Biol, vol. 45, no. 8, pp. 657-666, (2000).
	X188	Neuberger, M.S, et al, "Recombinant antibodies possessing novel effector functions", Nature, vol. 312, no. 5995, pp. 604-608, (1984).
	X192	Nosseri, C, et al, "Possible involvement of poly(ADP-ribosyl) polymerase in triggering stress-induced apoptosis", Exp Cell Research, vol. 212, no. 2, pp. 367-373, (1994).
	X195	Oyama, T, et al, "Nucleolar organizer regions are independently associated with a shortened survival in patients with non-small cell lung cancer", Surg Oncol, vol. 2, no. 6, pp. 341-347, (1993).
	X197	Paddison, P.J, et al, "Stable suppression of gene expression by RNAi in mammalian cells", Proc Natl Acad Science USA, vol. 99, no. 3, pp. 1443-1448, (2002).
	X199	Pandey, A, et al, "Proteomics to study genes and genomes", Nature, vol. 405, no. 6788, pp. 837-846, (2000).
	X202	Perry, S.W, et al, "Simultaneous in situ detection of apoptosis and necrosis in monolayer cultures by TUNEL and trypan blue staining", Biotechniques, vol. 22, no. 6, pp. 1102-1106, (1997).
	X205	Platt, N, et al, "Recognizing death: the phagocytosis of apoptotic cells", Trends Cell Biology, vol. 8, no. 9, pp. 365-372, (1998).
	X218	Richardson, D.S, et al, "Effects of PARP inhibition on drug and Fas-induced apoptosis in leukaemic cells", Adv Exp Med Biol, vol. 457, pp. 267-279, (1999).
	X220	Roninson, I.B, et al, "If not apoptosis, then what? Treatment-induced senescence and mitotic catastrophe in tumor cells", Drug Resist Update, vol. 4, no. 5, pp. 303-313, (2001).
	X226	Saikumar, P, et al, "Apoptosis: definition, mechanisms, and relevance to disease", Am J Med, vol. 107, no. 5, pp. 489-506, (1999).
	X232	Schmitt, C.A, et al, "Apoptosis is critical for drug response in vivo", Drug Resist Update, vol. 4, no. 2, pp. 132-134, (2001).
	X233	Sciavolino, P.J, et al, "Molecular biology of prostate development and prostate cancer", Ann Med, vol. 30, no. 4, pp. 357-368, (1998).
	X236	Sen, D, et al, "Formation of parallel four-stranded complexes by guanine-rich motifs in DNA and its implications for meiosis", Nature, vol. 334, no. 6180, pp. 364-366, (1988).
	X240	Sharp, P.A, "RNA interference - 2001" Genes Dev, vol. 15, no. 5, pp. 485-490, (2001).
	X247	Simbulan-Rosenthal, C.M, et al, "Involvement of PARP and poly(ADP-ribosyl)ation in the early stages of apoptosis and DNA replication", Mol Cell Biochem, vol. 193, no. 1-2, pp. 137-148, (1999).

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	X248	Sirri, V, et al, "Amount variability of total and individual Ag-NOR proteins in cells stimulated to proliferate", Histochem Cytochem, vol. 43, no. 9, pp. 887-893, (1995).
	X250	Smulson, M.E, et al, "Roles of poly(ADP-ribosyl)ation and PARP in apoptosis, DNA repair, genomic stability and functions of p53 and E2F-1", Adv Enzyme Regul, vol. 40, pp. 183-215, (2000).
	X255	Sperandio, S, et al, "An alternative, nonapoptotic form of programmed cell death", Proc Natl Acad Science USA, vol. 97, no. 26, pp. 14376-14381, (2000).
	X256	Srinivasan, S.K, et al, "Review of in vivo pharmacokinetics and toxicology of phosphorothioate oligonucleotides", J Clin Lab Anal, vol. 9, no. 2, pp. 129-137, (1995).
	X262	Stein, C.A, et al, "Phosphorothioate oligodeoxynucleotides-anti-sense inhibitors of gene expression?", Pharmacol Ther, vol. 52, no. 3, pp. 365-384, (1991).
	X266	Summerton, J, et al, "Morpholino antisense oligomers: design, preparation, and properties", Antisense Nucleic Acid Drug Development, vol. 7, no. 3, pp. 187-195, (1997).
	X267	Sundquist, W.I, et al, "Telomeric DNA dimerizes by formation of guanine tetrads between hairpin loops", Nature, vol. 342, no. 6251, pp. 825-829, (1989).
	X270	Symons, R.H. "Small catalytic RNAs", Annual Review Biochem, vol. 61, pp. 641-671, (1992).
	X272	Tanaka, Y, et al, "Inhibition and down-regulation of poly(ADP-ribose) polymerase results in a marked resistance of HL-60 cells to various apoptosis-inducers", Cell Mol Biol, vol. 41, no. 6, pp. 771-781, (1995).
	X273	Templin, M.V, et al, "Pharmacokinetic and toxicity profile of a phosphorothioate oligonucleotide following inhalation delivery to lung in mice", Antisense Nucleic Acid Drug Dev, vol. 10, no. 5, pp. 359-368, (2000).
	X277	Tockman, M.S, et al, "Sensitive and specific monoclonal antibody recognition of human lung cancer antigen on preserved sputum cells: a new approach to early lung cancer detection", J Clin Oncol, vol. 6, no. 11, pp. 1685-1693, (1988).
	X285	Wang, W, et al, "A comparison of guanosine-quartet inhibitory effects versus cytidine homopolymer inhibitory effects on rat neointimal formation", Antisense Nucleic Acid Drug Development, vol. 8, no. 3, pp. 227-236, (1998).
	X287	Wang, Y, et al, "Solution structure of the human telomeric repeat d[AG3(T2AG3)3] G-tetraplex", Structure, vol. 1, no. 4, pp. 263-282, (1993).
	X292	Williamson, J.R, et al, "Monovalent cation-induced structure of telomeric DNA: the G-quartet model", Cell, vol. 59, no. 5, pp. 871-880, (1989).
	X293	Winter, G, et al, "Making antibodies by phage display technology", Annu Rev Immunol, vol. 12, pp. 433-455, (1994).
	X294	Wolters, D.A, et al, "An automated multidimensional protein identification technology for shotgun proteomics", Anal Chem, vol. 73, no. 23, pp. 5683-5690, (2001).
	X300	Xue, Z, et al, "The amino terminus of mammalian nucleolin specifically recognizes SV40 T-antigen type nuclear localization sequences", Eur J Cell Biol, vol. 62, no. 1, pp. 13-21, (1993).
	X301	Yanagida, M, et al, "Isolation and proteomic characterization of the major proteins of the nucleolin-binding ribonucleoprotein complexes", Proteomics, vol. 1, no. 11, pp. 1390-1404, (2001).

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